

EPIPEN - epinephrine injection
EPIPEN JR - epinephrine injection
DEY

PRESCRIBING INFORMATION
(PHARMACIST - PLEASE REMOVE BEFORE DISPENSING)

EPIPEN® 0.3 mg EPINEPHRINE AUTO-INJECTOR

Auto-Injector for Intramuscular Injection of Epinephrine

For the Emergency Treatment of Allergic Reactions (Anaphylaxis)

Delivers a single 0.3 mg intramuscular dose of epinephrine from epinephrine injection, USP, 1:1000 (0.3 mL).

EPIPEN® JR 0.15 mg EPINEPHRINE AUTO-INJECTOR

Auto-Injector for Intramuscular Injection of Epinephrine

For the Emergency Treatment of Allergic Reactions (Anaphylaxis)

Delivers a single 0.15 mg intramuscular dose of epinephrine from epinephrine injection, USP, 1:2000 (0.3 mL).

IMPORTANT INFORMATION

- **DO NOT REMOVE GRAY SAFETY RELEASE UNTIL READY FOR USE.**
- **A SINGLE DOSE OF 0.3 ML OF SOLUTION IS DISPENSED. THE MAJORITY OF THE DRUG PRODUCT, 1.7 ML, REMAINS IN THE AUTO-INJECTOR AFTER ACTIVATION AND CANNOT BE USED.**
- **THE UNIT CONTAINS NO LATEX.**

DESCRIPTION

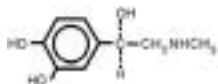
The EpiPen® and EpiPen® Jr auto-injectors contain 2 mL epinephrine injection for emergency intramuscular use. Each EpiPen auto-injector delivers **a single dose** of 0.3 mg epinephrine from epinephrine injection, USP, 1:1000 (0.3 mL) in a sterile solution.

Each EpiPen Jr auto-injector delivers **a single dose** of 0.15 mg epinephrine from epinephrine injection, USP, 1:2000 (0.3 mL) in a sterile solution.

For stability purposes, approximately 1.7 mL remains in the auto-injector after activation and cannot be used.

Each 0.3 mL in EpiPen contains 0.3 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0. Each 0.3 mL in EpiPen Jr contains 0.15 mg epinephrine, 1.8 mg sodium chloride, 0.5 mg sodium metabisulfite, hydrochloric acid to adjust pH, and Water for Injection. The pH range is 2.2-5.0.

Epinephrine is a sympathomimetic catecholamine. Chemically, epinephrine is B-(3, 4-dihydroxyphenyl)-a-methyl-aminoethanol, with the following structure:



It deteriorates rapidly on exposure to air or light, turning pink from oxidation to adrenochrome and brown from the formation of melanin. Epinephrine solutions which show evidence of discoloration should be replaced.

CLINICAL PHARMACOLOGY

Epinephrine is a sympathomimetic drug, acting on both alpha and beta receptors. It is the drug of choice for the emergency treatment of severe allergic reactions (Type I) to insect stings or bites, foods, drugs, and other allergens. It can also be used in the treatment of idiopathic or exercise-induced anaphylaxis. Epinephrine when given subcutaneously or intramuscularly has a rapid onset and short duration of action. The strong vasoconstrictor action of epinephrine through its effect on alpha adrenergic receptors acts quickly to counter vasodilation and increased vascular permeability which can lead to loss of intravascular fluid volume and hypotension during anaphylactic reactions. Epinephrine through its action on beta receptors on bronchial smooth muscle causes bronchial smooth muscle relaxation which alleviates wheezing and dyspnea. Epinephrine also alleviates pruritis, urticaria, and angioedema and may be effective in relieving gastrointestinal and genitourinary symptoms associated with anaphylaxis.

INDICATIONS AND USAGE

Epinephrine is indicated in the emergency treatment of allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise-induced anaphylaxis. The EpiPen and EpiPen Jr auto-injectors are intended for immediate self-administration by a person with a history of an anaphylactic reaction. Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritis, rashes, urticaria or angioedema. The EpiPen and EpiPen Jr are designed as emergency supportive therapy only and are not a replacement or substitute for immediate medical or hospital care.

CONTRAINDICATIONS

There are no absolute contraindications to the use of epinephrine in a life-threatening situation.

WARNINGS

Epinephrine is light sensitive and should be stored in the tube provided. Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Do not refrigerate. Before using, check to make sure the solution in the auto-injector is not discolored. Replace the auto-injector if the solution is discolored or contains a precipitate. Avoid possible inadvertent intravascular administration. EpiPen and EpiPen Jr should **only** be injected into the anterolateral aspect of the thigh. **DO NOT INJECT INTO BUTTOCK.**

Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. **DO NOT INJECT INTRAVENOUSLY.** Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine. Epinephrine is the preferred treatment for serious allergic or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may in other products cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations.

Accidental injection into the hands or feet may result in loss of blood flow to the affected area and should be avoided. If there is an accidental injection into these areas, advise the patient to go immediately to the nearest emergency room for treatment. EpiPen and EpiPen Jr should **only** be injected into the anterolateral aspect of the thigh.

PRECAUTIONS

Epinephrine is essential for the treatment of anaphylaxis. Patients with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens as well as idiopathic and exercise-induced anaphylaxis should be carefully instructed about the circumstances under which this life-saving medication should be used. It must be clearly determined that the patient is at risk of future anaphylaxis, since the following risks may be associated with epinephrine administration (see Dosage and Administration). Epinephrine is ordinarily administered with extreme caution to patients who have heart disease. Use of epinephrine with drugs that may sensitize the heart to arrhythmias, e.g., digitalis, mercurial diuretics, or quinidine, ordinarily is not recommended. Anginal pain may be induced by epinephrine in patients with coronary insufficiency.

The effects of epinephrine may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include: hyperthyroid individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, pediatric patients under 30 kg (66 lbs.) body weight using EpiPen, and pediatric patients under 15 kg (33 lbs.) body weight using EpiPen Jr.

Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen or EpiPen Jr to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which this life-saving medication should be used.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Studies of epinephrine in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted. This should not prevent the use of this life-saving medication under the conditions noted under INDICATIONS AND USAGE and as indicated under PRECAUTIONS above.

USAGE IN PREGNANCY

Pregnancy Category C: Epinephrine has been shown to be teratogenic in rats when given in doses about 25 times the human dose. There are no adequate and well-controlled studies in pregnant women. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC USE

Epinephrine may be given safely to pediatric patients at a dosage appropriate to body weight (see Dosage and Administration).

ADVERSE REACTIONS

Side effects of epinephrine may include palpitations, tachycardia, sweating, nausea and vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness and anxiety.

Cardiac arrhythmias may follow administration of epinephrine.

OVERDOSAGE

Overdosage or inadvertent intravascular injection of epinephrine may cause cerebral hemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary edema because of peripheral vascular constriction together with cardiac stimulation.

DOSAGE AND ADMINISTRATION

A physician who prescribes EpiPen or EpiPen Jr should take appropriate steps to insure that the patient (or parent) understands the indications and use of this device thoroughly. The physician should review with the patient or any other person who might be in a position to administer EpiPen or EpiPen Jr to a patient experiencing anaphylaxis, in detail, the patient instructions and operation of the EpiPen or EpiPen Jr auto-injector. Inject the delivered dose of the EpiPen auto-injector (0.3 mL epinephrine injection, USP,

1:1000) or the EpiPen Jr auto injector (0.3 mL epinephrine injection, USP, 1:2000) intramuscularly into the anterolateral aspect of the thigh, through clothing if necessary. See detailed Directions for Use on the accompanying Patient Instructions.

Usual epinephrine adult dose for allergic emergencies is 0.3 mg. For pediatric use, the appropriate dosage may be 0.15 or 0.30 mg depending upon the body weight of the patient. A dosage of 0.01 mg/kg body weight is recommended. EpiPen Jr, which provides a dosage of 0.15 mg, may be more appropriate for patients weighing less than 30 kg. However, the prescribing physician has the option of prescribing more or less than these amounts, based on careful assessment of each individual patient and recognizing the life-threatening nature of the reactions for which this drug is being prescribed. The physician should consider using other forms of injectable epinephrine if doses lower than 0.15 mg are felt to be necessary.

Each EpiPen or EpiPen Jr contains a single dose of epinephrine. With severe persistent anaphylaxis, repeat injections with an additional EpiPen may be necessary.

Parenteral drug products should be periodically inspected visually by the patient for particulate matter or discoloration and should be replaced if these are present.

HOW SUPPLIED

EpiPen[®] auto-injectors (epinephrine injections, USP, 1:1000, 0.3 mL) are available in individual cartons, NDC 49502-500-01, and as EpiPen 2-Pak[®], NDC 49502-500-02, a pack that contains two EpiPen auto-injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one EpiPen trainer device.

EpiPen[®] Jr auto-injectors (epinephrine injection, USP, 1:2000, 0.3 mL) are available in individual cartons, NDC 49502-501-01, and as EpiPen Jr 2-Pak[®], NDC 49502-501-02, a pack that contains two EpiPen Jr auto-injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one EpiPen trainer device.

Each EpiPen and EpiPen Jr auto-injector comes in an individual carrying case that provides built-in needle protection after use.

EpiPen 2-Pak and EpiPen Jr 2-Pak also include a S-clip to clip two cases together.

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Contains no latex. Protect from light.

Rx only.

MANUFACTURED FOR DEY[®], NAPA, CALIFORNIA 94558, U.S.A.

by Meridian Medical Technologies, Inc., a subsidiary of
King Pharmaceuticals, Inc., Columbia, MD 21046, U.S.A.

7/05 03-500-04
0001297

PATIENT INSERT

PHARMACIST, PLEASE DISPENSE WITH PRODUCT

EPIPEN[®]

(Epinephrine) Auto-Injector 015/0.3 mg

For allergic emergencies (anaphylaxis)

Amount of epinephrine delivered

EpiPen[®] = one dose of 0.30 mg epinephrine (USP, 1:1000, 0.3 mL)

EpiPen[®] Jr = one dose of 0.15 mg epinephrine (USP, 1:2000, 0.3 mL)

NDC 49502-500-01 (EpiPen[®])

NDC 49502-500-02 (EpiPen 2-Pak[®])

NDC 49502-501-01 (EpiPen[®] Jr)

NDC 49502-501-02 (EpiPen Jr 2-Pak[®])

MANUFACTURED FOR DEY[®]

NAPA, CA 94558, U.S.A.

**by Meridian Medical Technologies, Inc.,
a subsidiary of King Pharmaceuticals, Inc.,
Columbia, MD 21046, U.S.A.**

**03-535-04 2/06
0001323**

IMPORTANT INFORMATION

Please be prepared! Read both sides of this insert before an emergency occurs!

EpiPen[®] and EpiPen[®] Jr are disposable, prefilled automatic injection devices for use during allergic emergencies. They contain a single dose of epinephrine which you inject into your outer thigh.

EpiPen[®] and EpiPen[®] Jr contain **no latex**.

It's important that you have this emergency medicine with you at all times. If you need additional units to keep at work, school, etc, please talk to your doctor.

WHEN TO USE

EpiPen® and EpiPen® Jr auto-injectors are used to treat severe allergic reactions (anaphylaxis). You should use this medication only if your doctor has prescribed it for allergic emergencies. Such emergencies may occur from insect stings or bites, foods, drugs, latex, other allergens, exercise-induced anaphylaxis, or unknown causes.

CARE AND STORAGE

- Keep the EpiPen® or EpiPen® Jr auto-injector nearby and ready for use at all times.
- Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) (See USP Controlled Room Temperature). Contains no latex. Protect from light.
- **Do NOT** store in refrigerator.
- **Do NOT** expose to extreme cold or heat. For example, do NOT store in your vehicle's glove box.

Your auto-injector has an expiration date

- Example: "DEC 05" = December 31, 2005.
- Replace it before the expiration date.

To dispose of expired units

Expired auto-injectors must be disposed of properly.

To dispose of an expired auto-injector and carrier, take it to your doctor's office or to a hospital for proper disposal.

Examine contents in clear window of auto-injector periodically

- If the solution is discolored or contains solid particles (precipitate), replace the unit.
Solution should be clear.



Take advantage of the EpiPen® Center for Anaphylactic Support™—your FREE information resource for severe allergic reactions.

You'll receive expiration reminders, information about managing your severe allergic reactions, resource listings and valuable offers. To enroll please complete and mail the form below:

Mail to:
EpiPen® Center for
Anaphylactic Support™
DEY®
P.O. BOX 2000
Napa, CA 94558-9956

EpiPen® Center for Anaphylactic Support™ Enrollment Form

Please fill in the information below.

To ensure accuracy, please PRINT neatly in uppercase letters in black or dark-blue ink.

Your Name _____		
Child's Name (if child is allergy sufferer) _____		
Address _____		
City _____	State _____	ZIP _____
E-mail Address _____		
Opt-In: I would prefer to receive communications via e-mail: <input type="checkbox"/> Yes <input type="checkbox"/> No		
EpiPen®/EpiPen® Jr	Lot # (on unit, example 2ST059) <input type="text"/>	
	Exp. Date (on unit, example DEC05) <input type="text"/>	
Is this your first EpiPen® prescription or a refill? <input type="checkbox"/> First Prescription <input type="checkbox"/> Refill		
For what type of allergy was this EpiPen® prescribed?		
Check all that apply:		
<input type="checkbox"/> Food	<input type="checkbox"/> Insect bite or sting	
<input type="checkbox"/> Latex	<input type="checkbox"/> Medication	
<input type="checkbox"/> Other _____		



DIRECTIONS FOR USE

- **NEVER PUT THUMB, FINGERS, OR HAND OVER BLACK TIP.**
- **DO NOT REMOVE GRAY SAFETY RELEASE UNTIL READY TO USE.**
- **DO NOT USE IF SOLUTION IS DISCOLORED OR RED FLAG APPEARS IN CLEAR WINDOW.**
- **DO NOT PLACE PATIENT INSERT OR ANY OTHER FOREIGN OBJECTS IN CARRIER WITH AUTO-INJECTOR, AS THIS MAY PREVENT YOU FROM REMOVING THE AUTO-INJECTOR FOR USE.**



1. Unscrew the yellow or green cap off of the EpiPen[®] or EpiPen[®] Jr carrying case and remove the EpiPen[®] or EpiPen[®] Jr auto-injector from its storage tube.
2. Grasp unit with the black tip pointing downward.



3. Form fist around the unit (black tip down).
4. With your other hand, pull off the gray safety release.



5. Hold black tip near outer thigh.
6. Swing and **jab firmly** into outer thigh until it clicks so that unit is perpendicular (at a 90° angle) to the thigh. (Auto-injector is designed to work through clothing.)



7. Hold **firmly against thigh** for approximately 10 seconds. (The injection is now complete. Window on auto-injector will show red.)
8. Remove unit from thigh and massage injection area for 10 seconds.
9. Call 911 and seek immediate medical attention.
10. Carefully place the used auto-injector (without bending the needle), needle-end first, into the storage tube of the carrying case that provides built-in needle protection after use. Then screw the cap of the storage tube back on completely, and take it with you to the hospital emergency room.

Note: Most of the liquid (about 85%) stays in the auto-injector and cannot be reused. However, you have received the correct dose of the medication if the red flag appears in window.

WARNING

- **NEVER** put thumb, fingers, or hand over black tip. The needle comes out of black tip. Accidental injection into hands or feet may result in loss of blood flow to these areas.
If this happens, go immediately to the nearest emergency room.

- EpiPen[®] and EpiPen[®] Jr should be injected only into the outer thigh (see “Directions for Use”).
- Do NOT remove gray safety release until ready to use.

IMMEDIATELY AFTER USE

- **Go immediately to the nearest hospital emergency room or call 911.**
You may need further medical attention. Take your used auto-injector with you.
- Tell the doctor that you have received an injection of epinephrine in your thigh.
- Give your used EpiPen[®]/EpiPen[®] Jr to the doctor for inspection and proper disposal.

Join the Free EpiPen[®] Center for Anaphylactic Support[™] Today!

Because it's important that you always have an up-to-date EpiPen[®] or EpiPen[®] Jr with you at all times, we started an expiration reminder program as part of the EpiPen[®] Center for Anaphylactic Support[™]. Every time you purchase a new EpiPen[®], be sure to register it with us, and we'll send you reminders so you can have an up-to-date EpiPen[®].

This important program is a FREE service!

See other side for more details.

Revised: 02/2009

Distributed by: DEY